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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,756	10/16/2000	Fatih M. Uckun	12152.76USD1	1604

23552 7590 06/16/2003

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EXAMINER

LIU, HONG

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/16/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/688,756

Applicant(s)

UCKUN ET AL.

Examiner

Hong Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,34 and 46-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,34 and 46-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 31, 34, and 46-50 are pending in this application.

Rejection Maintained

Applicants' arguments were fully considered but were not found persuasive. Therefore, rejections to claims 47-50 under 35 U.S.C. 103(a) are maintained for reasons already made of record notwithstanding applicants' traverse.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 46, 31, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Uckun et al. (U S Patent 6,080,747). Uckun teaches the methods of using the compounds (see Table 1, col. 20).

Claim Rejections - 35 USC § 103

Claims 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. (WO 95/15758) is maintained for the reasons set forth in the office action mailed in paper No. 7 and 9. Applicants first argue that the mode of action of the reference compounds is to inhibit CSF-1R receptor tyrosine whereas the mode of action of the instantly claimed compounds is inhibition of JAK-3, a non-receptor tyrosine kinase. The distinction drawn by the applicants, although persuasive, is not particularly relevant in the nonobviousness analysis because the claims are not directed to subject matter of inhibition of JAK-3 or CSR-1R. Rather, the claims are drawn to a method of treating inflammation using the 6, 7-alkoxy quinazoline compounds. Therefore, the issue is whether the inflammation caused by CSF-1R abnormality is so different from the JAK-3-mediated inflammation that the reference compounds are only good at inhibiting autoimmune inflammation and the instantly claimed compounds are only effective in treating UVB-radiation induced inflammation. From what applicants' description of these two types inflammation, it appears that both UVB radiation caused inflammation and autoimmune inflammation involve activated macrophage and elevated levels of cytokines. If the quinazoline derivatives are effective in modulating the activated macrophage such that the production of the pro-inflammatory cytokines could be reduced, one would expect that the quinazoline compounds

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could be used to treat autoimmune inflammation and inflammation involving JAK-3 because of the similarity of the underlying mechanisms of these two types of inflammation. Absent experimental evidence showing that the reference compounds are indeed effective in treating autoimmune inflammation but not JAK-3-associated inflammation, applicants' conclusion that "compounds that might inhibit inflammation in the one may not inhibit inflammation in the other" does not seem to stand on a firm ground.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 46 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a UVB-induced inflammatory response using the quinazoline derivatives, does not reasonably provide enablement for use of any JAK-3 inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The nature of the invention in the instant application has claims which embrace a diversity of chemically and physically distinct compounds that can be JAK-3 inhibitors. While it is shown in Figure 17 that compound 6 can reduce an UVB-induced inflammatory response, there is no teaching in the specification that any JAK-3 inhibitors, which may not be limited to

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chemical compounds but antibodies or cytokines, could be as effective as compound 6 in reducing the inflammatory response.

This area of activity can be expected to be highly structure specific and unpredictable, as is generally true for chemically-based pharmacological activity. In view of the structural divergence in the claims, one skilled in the art could not reasonably extrapolate the activities of some of the claimed compounds to the other structurally divergent compounds embraced by the claims which have not been tested. In cases directed to chemical compounds which are being used for their physiological activity, the scope of the claims must have a reasonable correlation to the scope of enablement provided by the specification. See *In re Surrey* 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. No reasonable assurance has been made that the instant compounds as an entire class have the required activities needed to practice the invention. Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability” have been demonstrated to be sufficiently lacking in the instant case for the scope being claimed.

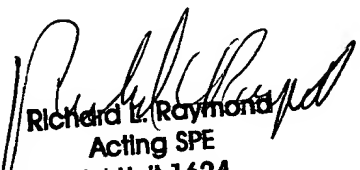
Because applicants’ amendments have not overcome the art rejection, this application is not deemed to be in condition of allowance.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. If attempts to reach the examiner by the phone are unsuccessful, the examiner’s supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for “unofficial” purposes and the actual

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number for official business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

Hong Liu
June 12, 2003


Richard L. Raymond
Acting SPE
Art Unit 1624
Mukund Shah
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